

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

THE UNITED STATES OF AMERICA, *ex rel.*
JULIE LONG,

Plaintiffs,

v.

JANSSEN BIOTECH, INC.,

Defendant.

Civil Action No. 16-CV-12182-FDS

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION TO ENTER
SCHEDULING ORDER**

TABLE OF CONTENTS

INTRODUCTION 1

RELEVANT PROCEDURAL HISTORY 3

 I. The Court’s Phased Discovery Rulings Have Placed This Case On A Path
 for Summary Judgment Rulings on Phase One. 3

 II. The Expansive Phase I Discovery Has Been More Than Sufficient to Test
 Relator’s Legal Theories..... 3

ARGUMENT..... 5

 I. The Purpose Of Phased Discovery Is To Provide For More Efficient
 Discovery And To Test Relator’s Legal Theories And Claims..... 5

 II. The Court Should Reject Relator’s Approach of Dramatically Expanding
 Discovery Nationwide, Particularly Since The Phase One Programs She
 Claims Were Kickbacks Were Applied Nationally. 7

 III. The Court Should Adopt Defendant’s Proposed Schedule..... 8

CONCLUSION..... 9

TABLE OF AUTHORITIES**Page(s)****Cases**

<i>United States ex rel. Chorchos for Bankr. Est. of Fabula v. Am. Med. Response, Inc.</i> , 865 F.3d 71 (2d Cir. 2017).....	7, 8
<i>United States ex rel. Chorchos for Bankr. Est. of Fabula v. Am. Med. Response, Inc.</i> , No. 3:12-CV-021-MPS, 2019 WL 4414951 (D. Conn. Sept. 16, 2019)	6, 7, 8
<i>United States ex rel. Chorchos for Bankr. Est. of Fabula v. Am. Med. Response, Inc.</i> , No. 3:12-cv-921 (MPS), 2018 WL 4350248 (D. Conn. Sept. 12, 2018).....	2, 6, 7, 8
<i>U.S. ex rel. Duxbury v. Ortho Biotech Prod., L.P.</i> , 719 F.3d 31 (1st Cir. 2013).....	6
<i>United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.</i> , Civ. No. 03-12189-RWZ, 2010 WL 3810858 (D. Mass. Sept. 27, 2010).....	5, 7, 8
<i>United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.</i> , Civ. No. 03-12189-RWZ, 2012 WL 3292870 (D. Mass. Aug. 13, 2012)	6
<i>United States ex rel. Johnson v. Golden Gate Nat'l Senior Care, L.L.C.</i> , No. CV 08-1194 (DWF/HB), 2020 WL 3072315 (D. Minn. June 10, 2020).....	2
<i>United States ex rel. Rost v. Pfizer, Inc.</i> , 253 F.R.D. 11 (D. Mass. 2008).....	<i>passim</i>
<i>United States ex rel. Rost v. Pfizer, Inc.</i> , 736 F. Supp. 2d 367 (D. Mass. 2010)	5

Statutes

Federal Anti-Kickback Statute.....	8
Federal False Claims Act.....	<i>passim</i>

Other Authorities

Federal Rule of Civil Procedure 16(b)(4)	1
Local Rules 16.1(g) and 26.3	1
Federal Rule of Civil Procedure 56(d).....	6, 8, 9

INTRODUCTION

In accordance with the Court’s directive to propose a “sensible framework” for evaluating the claims at issue in Phase One discovery during the August 2, 2021 hearing, and pursuant to Federal Rules of Civil Procedure 7(b) and 16(b)(4) and Local Rules 16.1(g) and 26.3, Defendant Janssen Biotech, Inc. (“Janssen”) submits this memorandum of law in support of its motion to enter an order scheduling the deadlines for the completion of Phase One fact and expert discovery and for briefing on motions for summary judgment. The proposed schedule incorporates the Court’s existing deadline for the close of Phase One fact discovery, November 15, 2021, and adds an efficient four months for the completion of expert and government discovery, with summary judgment motions on Phase One to be filed on March 15, 2022. On that date, Defendant will seek summary judgment on the programs covered by Phase One that Relator alleges specifically were kickbacks in violation of the False Claims Act (“FCA”).

Proceeding with summary judgment expeditiously will either end the case or, if claims remain, certainly narrow the case and provide for a substantially reduced discovery process in Phase Two. During the August 2, 2021 hearing, the Court recognized that “the entire point of phased discovery is to stop and say, all right, where are we? . . . Otherwise we may have just said on day one let’s do 50 state discovery of every program even if it’s 131 or 10,0031 [sic].” Status Conference Tr. 12:3–16, Aug. 2, 2021, ECF No. 161.

Setting a summary judgement schedule after Phase One accords with other courts in this District and beyond, beginning with the case on which Relator places principal reliance for her contrary approach, *United States ex rel. Rost v. Pfizer, Inc.* In *Rost*, Judge Saris did the opposite of what Relator claims—the Court in *Rost* ordered expert discovery and summary judgment

briefing at the close of fact discovery on Phase One, just as we propose here.¹ Other courts likewise imposed summary judgment schedules after phasing discovery in FCA cases.² In fact, Defendant is not aware of any court that has refused to entertain summary judgment at the close of phased discovery in an FCA case.

The Court should quickly reject the Relator's wasteful approach, which seeks to delay a ruling on the merits of her allegations that dozens of routine medical education and product support services provided by Janssen are kickbacks, and instead move on to nationwide discovery about such topics as the precise dates on which Janssen employees provided these medical education and support services—that Janssen claims are entirely lawful—to hundreds of physician practices across the nation. As the Court has already indicated:

[T]here is no point whatsoever in doing phased discovery if the only point of the discovery is to move on to another part of the discovery if nothing happens at the end of that phase of initial discovery. It's pointless. Otherwise, we may have just started with nationwide discovery. The whole idea of phased discovery is precisely that, to see is there something here?

Status Conference Tr. at 10:12–19, Aug. 2, 2021, ECF No. 161.

Instead, Defendant's proposed summary judgment proposal accords with the Court's prior guidance to the parties concerning the discovery schedule:

I think it's highly unlikely that what I'm going to say is, oh, well, now we've completed phase one, let's go on to phase two through

¹ Judge Saris ordered that “[a]ll fact discovery relating to the Indiana sales region shall be completed by February 15, 2009[,]” followed by plaintiff's expert report due March 15, 2009, defendants' expert report due April 15, 2009, and “[a]ny motion for summary judgment . . . filed by June 15, 2009.” *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 17 (D. Mass. 2008).

² See, e.g., *United States ex rel. Chorchos for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, No. 3:12-cv-921 (MPS), 2018 WL 4350248, at *2 (D. Conn. Sept. 12, 2018); *United States ex rel. Johnson v. Golden Gate Nat'l Senior Care, L.L.C.*, No. CV 08-1194 (DWF/HB), 2020 WL 3072315, at *1 (D. Minn. June 10, 2020) (noting discovery in FCA case was phased followed by summary judgment briefing, “such that Phase II would occur only if Relators' claims survived summary judgment as to Phase I”).

10,000. I'm going to want to know is there a sensible way for evaluating these claims at this point? And if they say they want to move for summary judgment, I'll say, all right. How do you propose to do that? And you'll have a chance to respond, including a Rule 56D response if you think that's fair. That's the way this is going to go. Okay?

Id. at 13:5–14.

RELEVANT PROCEDURAL HISTORY

I. The Court's Phased Discovery Rulings Have Placed This Case On A Path for Summary Judgment Rulings on Phase One.

The Court did not phase discovery just to determine if the challenged kickbacks were unique to Relator's former sales territory, or to determine if the challenged programs were nationwide. There was no dispute, for discovery purposes, that the challenged programs occurred outside of Relator's district. The Court phased discovery because .it was more efficient to first test these challenged programs in Relator's former sales district. *See* Mem. & Order on Def.'s Mot. Dismiss 33 n.12, ECF No. 75. Rather than simply determining whether the challenged programs occurred outside of Relator's territory – which was never in question – Phase 1 was to “inform a whole bunch of issues . . . about how discovery ought to proceed and what makes sense under the circumstances[.]” Scheduling Conference Tr. 4:18-20, Dec. 14, 2020, ECF No. 90.

II. The Expansive Phase I Discovery Has Been More Than Sufficient to Test Relator's Legal Theories.

Since the initial order directing phased discovery, the Court has also allowed that the core documents relating to Relator's personal knowledge and experience may be supplemented by certain high-level national custodians and categories of national documents that may inform the evaluation of Relator's allegations as to her specific region. *See* Docket Order, Apr. 6, 2021, ECF No. 114; Docket Order, Apr. 23, 2021, ECF No. 120.

Initially, the Court ordered Phase One discovery to “focus[] on Julie Long’s experience, what Julie Long was told, what she read, how she was trained, how she was supervised, what happened with these accounts that she worked with, you know, Dr. A, Dr. B, Practice A, Practice B, Practice C, et cetera.” Scheduling Conference Tr. 10:25–11:5, Dec. 14, 2020, ECF No. 90. Since then, discovery has been expanded to encompass many topics and documents outside of Relator’s former district. For one, Janssen produced the over 100,000 documents—all of which concern issues *outside* of Relator’s territory—that were previously produced to the U.S. Department of Justice in response to its Civil Investigative Demand related to this case, which were of course sufficient to persuade DOJ to decline to intervene. It was in fact these DOJ produced documents which Relator’s counsel stated to the Court “would 99 percent provide us the discovery that we generally need[.]” Status Conference Tr. 9:11–12, Mar. 23, 2021, ECF No. 109. Second, Defendant has or will soon complete production from four additional custodians chosen solely by Relator, all of whom worked at the national level as Sales Directors or Vice Presidents, and had little or no contact with Relator or with physician practice accounts in her sales territory. Third, Defendant has or will soon complete production of national-level documents from three senior marketing and compliance officials chosen by Relator, and who Relator’s counsel informed the Court were “the key witnesses in this case,” Letter from Relator’s Counsel to Chief Magistrate Judge Kelley 2 (July 9, 2021), and “people . . . who were at the core of making those decisions about some of these issues,” Mot. Hr’g Tr. 11:8–10, July 26, 2021, ECF No. 157. Finally, Defendant has or will soon complete the production of many additional “corporate” documents, including nationwide training materials, Janssen’s Promotional Review Committee (“PRC”) approval records for various presentations.

All told, by the close of fact discovery, Janssen will have produced millions of pages of documents; it has already produced more than 3 million pages to date, including production from the custodial email accounts of Relator and her direct supervisors.

Thus, there will be more than enough discovery for a summary judgment process to test Relator's kickback allegations in Phase One.

ARGUMENT

I. The Purpose Of Phased Discovery Is To Provide For More Efficient Discovery And To Test Relator's Legal Theories And Claims.

In phasing discovery, the Court adopted an approach of targeted discovery that has been applied with some variations in numerous FCA cases, which culminates with testing the relator's claims through the summary judgement process. For example, in *United States ex rel. Rost v. Pfizer, Inc.*, the court limited discovery to the geographic region as to which relator had made specific factual allegations in the complaint, even though the complaint alleged nationwide conduct. 253 F.R.D. at 17.

Contrary to Relator's obvious misreading of this case, Judge Saris ordered six months of fact discovery on the Indiana phase of the case *and then a four month process leading to summary judgment. Id.* Specifically, Judge Saris ordered that "[a]ll fact discovery relating to the Indiana sales region shall be completed by February 15, 2009," followed by the exchange of expert reports and "[a]ny motion for summary judgment . . . filed by June 15, 2009." *Id.*³

A similar process of limited discovery followed by summary judgment was applied by this district court in *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, Civ. No. 03-

³ At the close of the first phase of discovery, Judge Saris granted summary judgment on the relator's FCA claims. *United States ex rel. Rost v. Pfizer, Inc.*, 736 F. Supp. 2d 367 (D. Mass. 2010) (partially superseded by statute as stated in *Guilfoile v. Shields*, 913 F.3d 178 (1st Cir. 2019)).

12189-RWZ, 2010 WL 3810858 (D. Mass. Sept. 27, 2010). There, the court limited discovery to the geographic region of which relator had knowledge based on his former employment with the defendant. At the close of fact discovery, the defendant moved for summary judgment, which the district court granted because relator was unable to identify any evidence of fraud. *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, Civ. No. 03-12189-RWZ, 2012 WL 3292870 (D. Mass. Aug. 13, 2012). On appeal, the First Circuit affirmed the grant of summary judgment, finding the district court's discovery limitations "entirely consistent with the district court's considerable latitude in assessing the proper scope of discovery." *U.S. ex rel. Duxbury v. Ortho Biotech Prod., L.P.*, 719 F.3d 31, 39–40 (1st Cir. 2013).

The use of summary judgment to test allegations at the end of a phase of targeted discovery is the rule, not the exception, even in cases outside this District. In *United States ex rel. Chorchos for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, the district court adopted a phased discovery approach, with the first phase devoted to the specific claims identified in the complaint, the relator's employment retaliation claim, and a judicial estoppel argument raised by the defendant. No. 3:12-cv-921 (MPS), 2018 WL 4350248, at *2 (D. Conn. Sept. 12, 2018). Accordingly, the court entered a scheduling order that included a deadline for Phase One fact discovery and a deadline for defendant's dispositive motion based on Phase One fact discovery. *Id.* at *4. At the close of Phase One discovery, the defendant moved for summary judgment, which the Court granted in part and denied in part, allowing Relator to proceed on certain theories of liability in the complaint (but not on others). *United States ex rel. Chorchos for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, No. 3:12-CV-021-MPS, 2019 WL 4414951 (D. Conn. Sept. 16, 2019). Critically, the Court denied the Relator's Rule 56(d) motion, rejecting the argument that there was not adequate information in the summary judgment record, finding

that the discovery obtained in the first phase was sufficient to decide the motion for summary judgment. *Id.* at *21–22. The district court’s approach was consistent with the Second Circuit’s guidance on appeal in that matter, which observed that a qui tam relator’s claims may be tested through discovery of the specific false claims alleged in the complaint:

Where a *qui tam* relator identifies representative examples of false claims or, as here, makes allegations leading to a strong inference that specific false claims were submitted, defendants could initially be required to provide discovery only with respect to the cases identified in the complaint. If no genuine dispute of material fact is found to exist as to whether false claims were in fact submitted in that limited set of cases, the lawsuit would be at or near its end.

United States ex rel. Chorchos for Bankr. Est. of Fabula v. Am. Med. Response, Inc., 865 F.3d 71, 88 n.13 (2d Cir. 2017).

Here, as in *Rost*, *Duxbury*, and *Chorchos*, the Court should impose a summary judgment briefing schedule to test Relator’s fraud allegations involving the challenged programs. If, as in *Chorchos*, “no genuine dispute of material fact is found to exist as to whether false claims were in fact submitted in that limited set of cases, the lawsuit would be at or near its end.” *Id.*

II. The Court Should Reject Relator’s Approach of Dramatically Expanding Discovery Nationwide, Particularly Since The Phase One Programs She Claims Were Kickbacks Were Applied Nationally.

With virtually no support on the record, Relator now asserts that the sole purpose of phased discovery was to “confirm that the IOI Support services . . . were provided in Central Pennsylvania and to determine whether they were provided as part of a national directive.” Relator’s Reply Supporting Mot. to Compel, ECF No. 166, at 2; *see also* Relator’s Sept. 13, 2021 Mem. Supporting Mot. to Expand Discovery at 5–8 (Filed Under Seal). Neither Janssen nor the Court has ever endorsed this view of discovery; indeed, Janssen never disputed that the support programs under challenge occurred in regions outside of Relator’s former sales district. The fact that the challenged programs were repeated outside Relator’s district is a powerful

reason to phase discovery and then test the allegations at summary judgment, not the other way around.

Among other efficiencies to be gained by this approach, assessment of whether false claims were submitted in Central Pennsylvania is likely to be dispositive of multiple key issues, including whether any of the specific nationwide programs that are the subject of Relator's allegations was a kickback in violation of the Anti-Kickback Statute or False Claims Act. If after extensive Phase One discovery, Relator cannot show any AKS or FCA violations, "the lawsuit would be at or near its end." *Chorches*, 865 F.3d at 88 n.13. Regardless, Phase One is likely to resolve key legal issues applicable to alleged claims outside the Phase One universe (if any such claims remain), such as whether, or under what circumstances, the at-issue programs may constitute unlawful kickbacks in violation of the FCA.

This was exactly the outcome in *Rost*, *Duxbury*, and *Chorches*: in each, the court found that the record following a period of initial discovery was sufficient to grant summary judgment on claims alleged on a nationwide basis. Indeed, in *Chorches*, the Court denied relator's Rule 56(d) motion to deny or defer consideration of defendant's motion for summary judgment because requiring the defendant to produce more discovery as to lack of scienter "would defeat the rationale of the 'targeted discovery process' suggested by the Second Circuit[.]" *Chorches*, 2019 WL 4414951 at *21. The same considerations apply here.

III. The Court Should Adopt Defendant's Proposed Schedule.

Given the extensive discovery conducted in Phase One, summary judgment is a reasonable and appropriate way to proceed upon the close of fact discovery on November 15, 2021. Janssen intends to move for summary judgment as to whether the specific practice support

programs constituted kickbacks or are otherwise violative of the False Claims Act. Therefore, Janssen proposes the following schedule:

Close of Phase I Fact Discovery	November 15, 2021
Phase I Expert Reports Due	December 15, 2021
Phase I Rebuttal Expert Reports Due	January 28, 2022
Phase I Government Discovery Deadline	January 28, 2022
Phase I Expert Depositions Completed	February 28, 2022
Phase I Motions for Summary Judgment Due	March 15, 2022
<i>Daubert</i> Motions Challenging Expert Testimony Due	March 15, 2022
Opposition to Summary Judgment Briefs Due	April 15, 2022
Reply on Summary Judgement Briefs Due	April 30, 2022

The millions of pages of documents produced and remaining discovery to be taken before the November fact discovery deadline are more than enough to determine whether the specified programs were kickbacks.⁴

CONCLUSION

For the reasons discussed above, Janssen respectfully request that the Court grant its motion and enter an order scheduling the deadlines for motion for summary judgment briefing.

⁴ As the Court has recognized, if Relator believes it somehow needs more targeted discovery after the summary judgment motions are filed, she can file a motion under Fed. R. Civ. P. 56(d). See Status Conference Tr. at 11:22–12:2, Aug. 2, 2021, ECF No. 161.

Dated: September 20, 2021

s/ Sarah E. Tremont

Ethan M. Posner (admitted *pro hac vice*)
Michael M. Maya (BBO No. 672847)
Sarah E. Tremont (admitted *pro hac vice*)
Stacey K. Grigsby (admitted *pro hac vice*)
Covington & Burling LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000
eposner@cov.com
mmaya@cov.com
sgrigsby@cov.com
stremont@cov.com

Attorneys for Defendant Janssen Biotech, Inc.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing on this 20th day of September, 2021.

s/ Sarah E. Tremont

Sarah E. Tremont (admitted *pro hac vice*)